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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,439	01/05/2006	Stephen Robert Wedge	056291-5227	9937

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EXAMINER	
PACKARD, BENJAMIN J	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,439	WEDGE, STEPHEN ROBERT	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,7,8 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,7,8 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 03/10/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 3, 7, 8, and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (Journal of Clinical Oncology, Vol 20, No 18, 2002: pp 3815-3825), in view of Galligioni et al (Lung Cancer 34 (2001) S3-S7) and Malik et al (Targets, Vol. 2, No. 2 April 2003 pp 48-57).

Applicants assert (1) the applied references provide no suggestion or motivation to combine the references, but instead teach away from such a combination in favor of trying combinations of ZD2171 or ZD1839 with conventional cytotoxic drugs, but not with one another, (2) Kerkhoven holding with regard to combining sprayed detergents is not applicable to cancer therapies, and (3) comparative evidence of record demonstrates unexpected supper additive benefits.

First, with regards to the motivation, generally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Here, as outlined by Applicant, the primary reference

specifically teaches the compound ZD1839 may be used to treat NSCLC. The two secondary references suggest the VEGF pathway may be inhibited to treat NSCLC and that AZD2171 is an effective VEGF pathway inhibitor. Thus, the motivation to combine the references does not have to be explicit, but the prior art does teach the ability to combine treatments. The ability to combine the agents to produce a third composition used to treat the same disorder, i.e. NSCLC, would be obvious, given the resulting composition may be used to treat the same disorder.

While Applicants suggest there is a teaching away where the only combinations of the prior art are combinations of the separate components with cytotoxic agents, such is simply viewed as a preferred embodiment suggested by the prior art. As such, the prior art is utilized for all it teaches, including the use of the compound to treat the specific cancer and the ability to combine treatments, generally.

Second, while the factual pattern of Kerkhoven is not directly related to the instant claims, the legal analysis can be applied to different fact patterns. As cited, Kerkhoven supports the position that combining components to provide a final component is obvious; given the components to be combined have the same function as the resulting composition. Such is the reasoning made the in the instant rejection.

Finally, with respect to the supper-additive/synergistic effects, MPEP 716.02(d) states:

> "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

Here, the evidence presented (pg 17 lines 13-pg 18) are directed to treating mouse xenograph models with A431 vulval carcinoma tumor cells by concurrent oral administration of AZD2171 (3 mg/kg/administration) and ZD1839 (50 mg/kg/administration). While the evidence illustrated in figure 1 does support unexpected results of the disclose method specifically disclosed above (where the reduction of mean tumor volume does not occur for separate administration), it does not support the broader scope of the claims, given the claims may be interpreted to include separate administrations (before or after each other) or to colon, breast, prostate, and lung cancers generally.

Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (Journal of Clinical Oncology, Vol 20, No 18, 2002: pp 3815-3825), in view of Galligioni et al (Lung Cancer 34 (2001) S3-S7), Malik et al (Targets, Vol. 2, No. 2 April 2003 pp 48-57), and Weichselbaum et al (US 6,420,335, see 892 dated 12/10/2007).

Applicant does not discuss this rejection separately, but instead appears to combine the above rejection with the addition of the final art, Weischselbaum. With regard to Weischselbaum et al, Applicants assert ionization radiation is taught in combination with anti0angiogenic factors, which have quite different activity of small molecule inhibitors, such as AZD2171.

The response to the rejection above is disclosed above.

In response to the addition of Weischselbaum et al, Examiner simply cited this art for the teaching that ionization treatment is a known treatment for NSCLC. As such, as discussed above, it is prima facia obvious to combine treatments where the treatments are used to treat the same common disorder. Further, in the instant claims, the administration of the various treatments are not required to be simultaneous, so it would be further obvious to try the various treatments when trying to treat NSCLC.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612